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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,863	05/01/2001	Philip Goelet	13020-2-D1	5388

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Kalow & Springut LLP
488 Madison Avenue, 19th Floor
New York, NY 10022

EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
02/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/846,863	GOELET ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-59 and 61* is/are rejected.

7)☒ Claim(s) *60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *30 October 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 30 October 2007 has been entered.

Specification

2. The disclosure is objected to because of the following informalities:

a. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

b. As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. In the present case it is noted that the first paragraph of the specification is not directed to cross-reference to related application. While an amendment to the specification was made on 06 May 2005, the placement of this paragraph has not been changed.

4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 32-59 and 61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of claim 60, does not reasonably provide enablement for the identification and use of those single nucleotide polymorphisms in any species of any mammal that have some utility. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The quantity of experimentation necessary

The quantity of experimentation is great- on the order of several man-years with little if any reasonable expectation of ever being fully enabled. Indeed, in the 14 years post the claim for priority, the full enablement still ahs not been achieved

The amount of direction or guidance presented,

The amount of guidance provided is limited.

The presence or absence of working examples

The specification has been found to provide the following examples:

- Example 1, "Discovery of Equine Polymorphisms," pp. 45-47;
- Example 2, "Characterization of Equine Polymorphisms," pp. 47-50;
- Example 3, "Allelic Frequency Analysis of Equine Polymorphisms in Small Population Studies" (50-60 animals), pp. 50-54;
- Example 5, "Parentage Testing" (equine), pp. 55;
- Example 5, "Identity testing," pp. 56-58; and
- Example 6, "Analysis of a Human SNP," pp. 58-62.

Of the six examples provided, none disclose how one would test and evaluate the myriad "species of interest," much less identify said single nucleotide polymorphisms in a simultaneous manner any number of individuals (claims 32, 36-39, and 43-45), or when testing 10,000 individuals (limitation of claims 35 and 42).

While the specification does present several examples, such are directed to the analysis of but equine and human DNA and then primarily to the analysis of equine DNA as it relates to

parentage analysis (Example 4). Said six examples do not provide an adequate written description of the claimed method whereby one would be able to determine any and all single nucleotide polymorphisms in any and all species of mammals. As presently worded, the claimed method fairly encompasses performing the identification when but one strand is sequenced and/or is present in but only one haploid example. Page 47 of the disclosure, however, teaches, "Differences were concluded to be a DNA polymorphism only if the data was available for both strands, and/or present in more than one haploid example among the five horses tested." The specification does not provide an adequate written description of how to practice the full scope of the invention where but one strand is analyzed and/or where the frequency of the polymorphism is less frequent than 1 in 5, be the species human, equine, or non-human primate, dogs, cats, cattle, or sheep, as is recited in claim 48 and 53.

Example 1 clearly teaches that equine polymorphisms were identified in the breed of horses known as thoroughbred. The specification has not provided any teaching that polymorphisms found in one breed is also found in another breed, especially when the phenotype of the breeds is highly divergent, which in turn fairly suggests that the genetic makeup of the two equines is highly dissimilar, e.g., the Lithuanian Heavy Draft and the Noma, where the Lithuanian Heavy Draft was first recognized in 1964, with the Noma originating in the seventeenth century. While both are horses, the existence of one for centuries and the non-existence of the other until a few decades ago speaks to their genetic diversity. The specification fails to provide an adequate written description of how one would recognize and use single nucleotide polymorphisms (SNPs) in one breed to in turn recognize an individual in another breed, much less determine paternity.

The nature of the invention and breadth of claims

In accordance with claims 32-38 and 46-52, one is identifying the presence of single nucleotide polymorphisms (SNP) in any mammal. The SNP does not have to be associated with any specific trait, much less have any specific, substantial, or credible utility. The specification is essentially silent s to how one would be able to identify useful SNPs from those that are not, and to then be able to use them in a method that meets the utility requirements.

Claims 39-45 and 53-55 are drawn to a method of determining allelic frequency at a SNP site. Claims 56-58 are drawn to determining parentage in equine, with claims 59-61 being drawn to determining parentage in any mammal.

The state of the prior art

Nickerson et al., teach in their 2001 article:

> One problem, common to all methods of SNP and mutation detection, is that experimental conditions required for detection of DNA sequence variants depend on the specific DNA sequence to be analyzed. Although algorithms and other calculations have been developed to predict the experimental conditions required to detect DNA sequence variation in a specific DNA sequence, these algorithms do not always provide reliable information and experimental conditions for SNP and mutation detection must be devised empirically. Determination of experimental conditions for detection of DNA sequence variation is difficult when samples containing only wild type sequence are available.

As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and

physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

In view of art-recognized unpredictable nature of the art, greater level of disclosure is required for enablement.

The predictability or unpredictability of the art

As seen above, the predictability of the art is low, as the conditions used to detect the presence of SNP must be devised empirically. The specification provides at best one set of conditions, and those were for a specific breed of horses. There is no showing that the same conditions work for any other breed, much les other species. In view of the 2001 article cited above, there is no reason to expect that one condition would work for sample from another individual, or for a sample from a different tissue/source in the same individual.

8. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.

Response to argument

9. At page 10 of the response received 30 October 2007, hereinafter the response, applicant's representative asserts that one of skill in the art would have interpreted the claims in the same manner as the Office. This argument is essentially a repeat of the argument found at page 12 of the response received 04 January 2007. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

10. It is noted that in accordance with independent claims 32, 39, 59, and 61, there is no limitation on the term "mammal." Further, dependent claims 33-38 and 40-47 do not recite any limitations as to they type(s) of species of mammals to be encompassed. In the absence of convincing evidence to the contrary, the claims are given their broadest reasonable interpretation. Attention is directed to MPEP 2111:

> **2111 [R-5] Claim Interpretation; Broadest Reasonable Interpretation**
> **CLAIMS MUST BE GIVEN THEIR BROADEST REASONABLE INTERPRETATION**
>
> 415 F.3d at 1316, 75 USPQ2d at 1329. See also< In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified.

11. At page 11 of the response, argument is presented that "SNPs occur with greater allelic frequency and uniformity and thus can be linked to an individual trait. SNPs are more stable than other classes of polymorphisms...a SNP's allelic frequency can be inferred from a small number of representative samples... [and] SNPs allow a high degree of genetic information (e.g., base position and location) unlike other types of polymorphisms."

12. It is noted with particularity that no showing has been made that information regarding SNPs frequency of occurrence, intrinsic information, and relative sample size in horses and humans is applicable to other, widely divergent species of mammals.

13. At page 11, bridging to page 12, said representative asserts that impermissible hindsight was used in interpreting the claims as simultaneous sequencing was not invented until about 2002, "which is well after the filing date of the present application."

14. In view of the agreement that the claims do encompass such an embodiment, and that the technology was not developed until about 9 years post filing of the priority date of the instant application, it is not possible for applicant to have enabled such. As for the use of hindsight to interpret claim scope,

15. At page 12 of the response argument is presented that starting material is provided, and that the specification is fully enabled.

16. The above argument has not been found persuasive as the specification does not provide starting materials for an adequate number of species so as to reasonably suggest that applicant had possession of the claimed genus. As noted above, independent claims 32, 39, 59, and 61, do not limit the term "mammal." Further, dependent claims 33-38 and 40-47 do not recite any limitations as to the type(s) of species of mammals to be encompassed.

17. The specification only provides equine SNPs, and a method for establishing parentage in equines. The methods, however, are not limited to equines. As seen in claim 53, for example, the "mammal is selected from the group consisting of human, non-human primates, dogs, cats, cattle, sheep, and horses."

18. While the specification has been found to contain a showing that some equine SNPs are useful in identifying a source, the specification has not been found to enable a method whereby one would be able to readily determine which SNPs, if any, are useful for any mammal for any purpose. The specification has not presented any showing that equine SNPs are useful in identifying he source, condition, or parentage of any other species and as such, the showing of various SNPs in equine has no effect on one being able to analyze non-equine mammalian samples. In support of this position attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.
>
> ***
>
> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

19. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled to the full extent of the claims' scope. Applicant is urged to consider narrowing the claims to those embodiments that are deemed to be adequately enabled by the original disclosure.

20. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

21. Claims 32-45, 48, and 51-55 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

22. As presently worded, the claimed method is to result in the identification of single nucleotide polymorphisms from any and al manner of species of mammals. The polymorphic site is not required to be useful for any method. Accordingly, the claim has been construe as encompassing the identification of SNPs that do not meet the utility requirements of 35 USC 101.

23. Claims 32-45, 48, and 51-55 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

26. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

27. Claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al.

28. Erlich et al., Figure 1, Table 1, Figure 2 and corresponding legend and Figure 3, teach a method of identifying single nucleotide polymorphic sites in a genome of interest. As seen in the chart/table at pages 38-39, at least 18 different DNA sequences were evaluated with specific SNPs explicitly identified through comparison with other sequences. Such a showing meets a limitation of claim 33-35 and 40-42.

29. As set forth in the title and abstract, the method comprises the performance of PCR. Accordingly, a limitation of claims 38 and 45 has been met.

30. Erlich et al., page 34, teaches analysis of a human chromosome six. Such a showing meets a limitation of claims 48, 51, 53, 54, and 59.

31. To the degree that claims recite limitations as to the specific size of a test grouping, or of the fragment size or detection means, such limitations are not deemed to rise to the level of a patentable distinction but rather, are the result of routine optimization. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

> Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136.

32. For the above reasons, and in the absence of convincing evidence to the contrary, claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al.

33. Claims 33-35, and 39-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al., as applied to claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 above, and further in view of Fey et al.

34. See above for the basis of the rejection as it pertains to the disclosure of Erlich et al.

35. Fey et al., teach using DNA polymorphisms in identifying parentage, and that the method can be applied to humans, and more broadly to animals and plants (page 821), and the species of each. Fey et al., page 818, teaches using polymorphisms associated with HLA.

36. Accordingly, and in the absence of convincing evidence to the contrary, claims 33-35, and 39-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al., as applied to claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 above, and further in view of Fey et al.

37. In view of the prior art teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the disclosures of Fey et al., with that of Erlich et al., as the application of DNA polymorphisms would have allowed the ordinary artisan to apply the technology to screening of relatedness between species and well as between members of a species, including the identification of parentage. In view of the detailed description provided, and the desire of such technology in the work place, the ordinary artisan would have been highly motivated and would have had a most reasonable expectation of success.

Response to argument

At page 13 of the response of 30 October 2007, hereinafter the response, argument is presented that:

> Erlich teaches typing the HLA gene using allele specific oligonucleotide probes (ASO) that hybridize to HLA class II polymorphisms DQA1, DQB1, DRB1, and DPB1. These

> HLA class II polymorphisms are polymorphic regions and not single nucleotides polymorphisms. The allele specific probes listed in Table 1, which the Examiner refers to, do not discriminate among alleles that differ by a single nucleotide base. If the ASO probes did, they would differ by one nucleotide base as well. Figure 3, which the Examiner also refers to, illustrates the DNA sequence and probe alignments for the probes listed in Table 2. Note the DNA locus and probe alignments listed in Table 2 of Erlich and the regions he interrogates have multiple nucleotide variations and could not and are not considered single nucleotide polymorphisms that are immediately flanked by a 3' and 5' invariant nucleotide sequence as currently claimed.

The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. In accordance with claim 32, all one needs to do to meet the claim limitation is to sequence corresponding DNA fragments format east two individuals and then compare the results to see if there are any single nucleotide polymorphisms. As set forth in claim 32, the aspect of what constitutes a SNP is define thusly: "wherein each single nucleotide polymorphism is immediately flanked by a 3' and 5' invariant nucleotide sequence and the species of interest is a mammal and the comparison is made among mammals of the same species."

38. For purposes of examination, the expression "a 3' and 5' invariant nucleotide sequence" has been construed to require that at least 2 nucleotides found 3' and 5' of the SNP that do not vary. As noted above, the claim does not require the same probes be used to sequence the same regions in different sources of nucleic acid. Further, the claims do not require that one only be looking for a single nucleotide polymorphism. As produced in the prior Office action, and for convenience, reproduced below, Figure 3 of Erlich clearly and explicitly teaches sequencing of human DNA, and comparing the sequences so to identify any SNP present. The fact that Erlich may have also found additional information does not take away from this explicit teaching nor render the claimed method non-obvious.

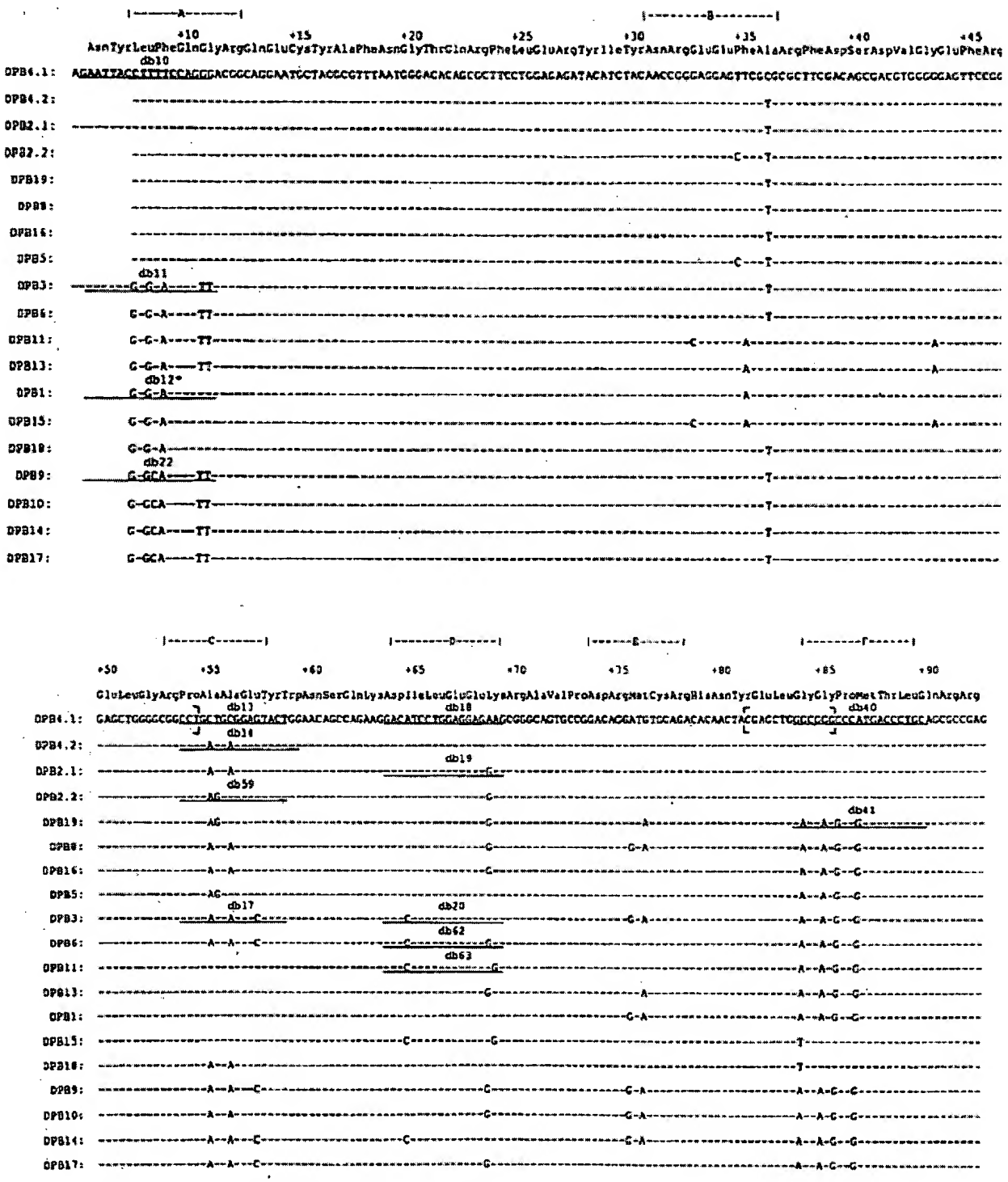

FIG. 3. DPB1 locus DNA sequences and probe alignments (cf. Table 2).

39. At page 14 of the response, argument is presented that "Fey, like Erlich, does not disclose, each or suggest utilizing SNPs." This argument ahs not been found persuasive for as shown above, Erlich does disclose the identification of single nucleotide polymorphisms. Fey, in the abstract, states: "DNA polymorphisms are based on variations in the nucleotide sequences of the DNA within a given population and are transmitted from parents to offspring by Mendelian inheritance." Such explicit language unquestionably ties the importance of polymorphisms to lines of inheritance, which is recognized as occurring not only within a family, but along lines of a species.

40. Attention is directed to the decision in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007)

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

41. It is further noted that prior art is not limited to the four corners of the documentary prior art being applied. Prior art includes both the specialized understanding of one of ordinary skill in the art, and the common understanding of the layman. It includes "background knowledge possessed by a person having ordinary skill in the art. . . [A] court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR* at 1396.

42. Suggestion, teaching or motivation does not have to be explicit and "may be found in any number of sources, including common knowledge, the prior art as a while or the nature of the

problem itself'" *Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007) citing *Dystar Textilfarben GMBH v. C. H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006).

43. For the above reasons, and in the absence of convincing evidence to the contrary, the rejections of claims under 35 USC 103(a) is maintained.

Conclusion

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

46. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner
Art Unit 1634

BLS